MAY 15 2014
K130915

510(k) Summary

1.) Safety and effectiveness as required by 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2.) Submitter's / Owner of the 510(k) and Contact Information

Name: JAS Diagnostics

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Miami Lakes, FL 33014

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Official Correspondent
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Date of Preparation
April 14, 2014

510(k) Application Number
K130915

3.) 510k Number, Device, Proprietary Name, Common Name, Purpose for Submission, Regulatory Classification, Panel, Product Code And CFR Number

Regulation Number:	Device Description
21CFR Sec. – 862.2160	Discrete Photometric Chemistry Analyzer for Clinical Use
21CFR Sec. – 862.1345	Glucose Test System
21CFR Sec. – 862.1665	Sodium Test System
21CFR Sec. – 862.1600	Potassium Test System
21CFR Sec. – 862.1170	Chloride Test System

Classifications:
Class II and Class I (Analyzer)

Product Codes
JJE – Analyzer, Chemistry (Photometric, Discrete), for Clinical Use
CFR – Hexokinase, Glucose
JGS – Electrode, Ion Specific, Sodium
CEM – Electrode, Ion Specific, Potassium
CGZ – Electrode, Chloride

Panel
Chemistry (75)

4.) Proprietary Name and Common Name

Trade/Proprietary Name
XL-200 Clinical Chemistry Analyzer, JAS Glucose Reagent, ISE Reagent Pack

Common Name/Usual Name
XL-200 Clinical Chemistry Analyzer, JAS Glucose Reagent, ISE Reagent Pack

5.) Indications for Use

The XL-200 Clinical Chemistry Analyzer is an automated, random access, computer controlled, bench top clinical chemistry analyzer for clinical chemistry tests. The instrument provides in vitro quantitative measurements for glucose, sodium, potassium, and chloride in serum. This device is intended for clinical laboratory use.

The JAS Glucose Reagent in intended for the in vitro quantitative measurement of glucose in serum on the XL-200 Clinical Chemistry Analyzer. This device is intended for clinical laboratory use. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and of pancreatic islet cell carcinoma.

The ISE Reagent Pack is intended for the in vitro quantitative measurement of sodium, potassium, and chloride concentrations in serum on the XL-200 Clinical Chemistry Analyzer. This device is intended for clinical laboratory use.

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus and other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

6.) Device Description: JAS XL-200 Clinical Chemistry Analyzer

The XL-200 Clinical Chemistry Analyzer is an automated bench top, random access, open analyzer for clinical chemistry and immunoturbidimetric analysis on serum, urine, and other body fluids. The analyzer mainly uses colorimetric, turbidimetric, and ion selective electrode methods for analysis of samples.

The instrument includes of the following main parts;

- Sampling Arm (for sample addition to cuvettes)
- Reagent Arm (for reagent addition to cuvettes)
- Reaction Station (cuvettes)
- Sample Plate Station (for loading samples)
- Reagent Plate Station (for on board reagents)
- Photometer (for reaction analysis reading)
- Wash Station (for cleaning of reaction cuvettes)
- Electronic Boards (for controlling the open functions)

7.) Substantial Equivalence Information:

1.) Predicate 510(k) number: K981743
2.) Olympus AU400 Clinical Chemistry Analyzer:
3.) Comparison to predicate:

	Device Name	Device: XL-200 Clinical Chemistry Analyzer	Predicate Device: OLYMPUS AU400 Clinical Chemistry Analyzer
1	510(k)	Pending	K981743

2	**System Principles**		
	QC/Calibration	Automatic and Manual	Automatic and Manual
	LIS external connectivity	YES	YES
	Barcode	Samples Reagents	Samples Reagents
	Re-dilution on abnormals	YES	YES
3	**Throughput**	200 test/hour 400 with ISE	400 test/hour 800 with ISE
4	**Principle of analysis**		
	Mode of detection	Photometric / ISE	Photometric / ISE
	Analytical Methods	Endpoint, Kinetic, Ion Selective Electrodes	Endpoint, Kinetic, Ion Specific Electrodes
	Calibration	Linear and non linear	Linear and non linear
5	**Optical measurement unit**		
	Measurement modes	Absorbance	Absorbance
	Optical modes	Bichromatic, turbidimetric	Bichromatic, turbidimetric
	Wavelengths	340nm, 405nm, 505nm, 546nm, 578nm, 600nm, 660nm, 700nm	340nm, 380nm, 410nm, 450 nm, 480nm, 520nm, 540nm, 570nm, 600nm, 660nm , 700nm, 750nm 800nm
	Linear absorbance range	0.0 to 2.5 A	0 to 2.5 A
	Light source	halogen lamp	halogen lamp
	Detector	Silicone photodiode array	Silicon photodiodes

6	**Reaction unit**		
	Reaction cuvettes	45 quartz semi-disposable	88 quartz semi-disposable
	Reaction volume	180 to 570 uL	180 to 610 uL
	Path length	Calculated at 10mm	10mm conversion
	Temperature	Room, 30°C, 37°C	Room, 30°C, 37°C
7	**Sample and reagent unit**		
	Reagent positions	25 for Rgt1, 50mL bottles 25 for Rgt2, 20mL bottles	38 for Rgt1, 60mL bottles 38 for Rgt2, 15 & 30mL bottles
	Sample positions	39	48
	Pipetter system	plunger, stepper motor driven	Micro-syringe, motor driven
	Mixing	Immersion mixing by rotating mixers	Rotating mix bar
	Reagent refrigeration	YES	YES
	Sample dispensing	2 - 70 microliters	2 - 50 microliters
8	**Power**	AC220V. 50 Hz or 110v, 60Hz	AC210V, 60Hz (U.S.)
9	**Environmental conditions**	15 to 30°C, Humidity 40 to 80%	15 to 30°C Humidity 40 to 80%
10	**ISE Principle**	Ion selective, direct measurement	Ion selective, direct measurement
11	**ISE sample type**	Serum	Serum, Urine

12	**Available tests**	Na, K, Cl	Na, K, Cl
13	**ISE calibration**	Two-point and single point	Two-point and single point
14	**Sample size**	70 uL	70 uL

8.) Device Description: JAS Glucose Reagent

The JAS Glucose Reagent is intended for the quantitative measurement of glucose in serum on the XL-200 Clinical Chemistry Analyzer. The Reagent is a single vial liquid that is placed for use on the XL-200 Clinical Chemistry Analyzer reagent carousel. The reagent uses the enzymatic (Hexokinase/G-6-P) UV (340nm) method. This device is for clinical laboratory use.

9.) Substantial Equivalence Information:

Predicate 510(k) number: K981743
Olympus AU400 Clinical Chemistry Analyzer, Glucose Reagent

10.) Comparison to predicate:

Manufacturer:	**JAS Diagnostics**	**Beckman Coulter Olympus**
Device Name	JAS Glucose Reagent for XL-200 Clinical Chemistry Analyzer	Olympus Glucose Reagent for Olympus AU 400 & 600 series Chemistry Analyzers
	JAS Diagnostics	**Beckman Coulter (Olympus)**
FDA 510k #	K130915 (CFR) (Pending)	K981743 (CFR)
Classification	Moderate (Pending)	Moderate

Intended Use	quantitative measurement of glucose in serum on the XL-200 Clinical Chemistry analyzer *For clinical laboratory use*	quantitative measurement of glucose in serum, plasma, urine, on Beckman Coulter clinical chemistry analyzers *For clinical laboratory use*
Methodology	enzymatic (Hexokinase / G-6-P), UV (340nm)	enzymatic (Hexokinase / G-6-P), UV (340nm)
Reagent Description	Single vial liquid reagent	Two vial liquid reagent
Normal Range		
Adult	74 – 106 mg/dL	70 -105 mg/dL

11.) Performance Characteristics - Glucose

Linearity

Protocol: 9 Serial Dilutions of a 500 mg/dL Glucose Standard were prepared and run on the XL-200, along with the 500 mg/dL stock Standard. Results were then plotted as a regression graph against theoretical recovery.

Results: Acceptable Slope 1.001 and Intercept of -0.1mg/dL, and data linear within allowable nonlinearity of 3mg/dL or 5% resulted; validating the product's claimed linearity range of 9 to 500mg/dL.

Calibrator Traceability:

Protocol: Verichem Laboratories Matrix Plus Chemistry Reference Kit (9500) five level reference material was run on the XL-200 Clinical Chemistry Analyzer, using JAS Glucose Reagent. This material is "Verified and lot certified using available standard reference materials for the National Institute of Standards and Technology (NIST)."

Results:
Program's Evaluation of glucose Results states accuracy test passed and results linear; with a slope of 0.972 and intercept of 2.1mg/dL, with error of 1.4%.

Interferences

Protocol: Serial dilutions were prepared using a high interferent sample material, with the same sample material (glucose level) without the interferent spiked. Acceptable interference level is the is the highest interferent sample level were the glucose values remains within 10% of the sample value unspiked with the intereferent.

Results: The following highest interferent levels for the sample, with < 10% interferent were obtained.

Hemoglobin	up to 400 mg/dL
Bilirubin	up to 21.4 mg/dL
Lipemia	up to 412 mg/dL
Ascorbic Acid	up to 10.0mg/dL

Correlation

Protocol: Multiple serum samples, at various glucose levels, were run on multiple days through the test's analytical range on the XL-200 clinical chemistry analyzer, using JAS Glucose reagent and also on the Olympus 400, using Olympus Glucose reagent. Results were compared using a correlation plot.

Results: The following acceptable statistics resulted, i.e. $R > 0.95$, Slope between 0.90 and 1.10, and intercept close to 0 mg/dL level.

JAS Glucose reagent on the XL-200 Clinical Chemistry Analyzer versus Olympus glucose reagent of Olympus 400:

Number of sample pairs:	103
Range tested: x method	11 to 497 mg/dL
y method	9 to 501 mg/dL
Corr. Coef. (R)	0.9970
Slope	1.002
Intercept	1.8 mg/dL

Precision/Reproducibility:

Protocol: Precision was performed using "EP Evaluator's NCCLS EP5-T2 Precision document (NCCLS.EP5)" program. Three glucose sample levels were run 20 times in duplicate, using 20 runs over a 20 day period on the XL-200 Clinical Chemistry Analyzer, for within run and for total imprecision calculation/determination.

Results: Results were entered into Rhoads EP Evaluator Software for determining precision S.D. and CV levels. All results below meet requirement of CV (%) < 5% for both within and total precision.

Glucose

Within Run	Level 1	Level 2	Level 3
Mean (mg/dL)	49.8	96.2	303.4
S.D. (mg/dL)	0.9	1.1	3.6
C.V. (%)	1.7	1.2	1.2
Total			
S.D. (mg/dL)	1.3	1.8	3.8
C.V. (%)	2.6	1.8	1.3

12.) Device Description: ISE Reagent Pack (for use on the XL-200 Clinical Chemistry Analyzer)

Comparison to Beckman Coulter Olympus 400:

		XL-200 Clinical Chemistry Analyzer	Beckman Coulter Olympus AU400
1	**ISE Principle**	Ion selective, direct measurement	Ion selective, direct measurement
2	**ISE sample type**	Serum	Serum, Urine
3	**Available tests**	Na, K, Cl	Na, K, Cl
4	**ISE calibration**	Two-point and single point	Two-point and single point
5	**Sample size**	70 uL	70 uL

Device Description: The JAS ISE Module consists of ion selective electrodes for sodium, potassium, and chloride, a reference electrode and accessory reagents.

XL-200 Clinical Chemistry Analyzer
ISE Solutions:

***ISE Reagent Pack: REF: 5423-0030:**
Calibrant A, 520mL:
(Na 140.0, K 4.00, Cl 125.0 mmol/L)

Calibrant B, 190mL:
(Na 70.0, K 8.00, Cl 41.0 mmol/L)

***REF 5421 Cleaning Solution**

Beckman Coulter Olympus ISE Solutions:

ISE Buffer, PN: AUH1011
ISE Reference, PN: AUH1013
ISE Mid Standard, PN:AUH1012

Internal Reference Solution, PN: AUH1017
ISE Low Standard, PN: 1014
ISE High Standard, PN: 1015
Na Selectivity Check, PN: AUH1018

XL-200 Clinical Chemistry Analyzer; Electrodes:
***REF 5201: Na Electrode**
***REF 5202: K Electrode**
***REF 5207: Cl Electrode**
***REF 5204: Reference Electrode**

14.) Substantial Equivalence Information for ISE Reagent Pack:

1.) Predicate 510k number: K981743
2.) Manufacturer: Beckman Coulter (Olympus)

3.) Comparison to predicate: See below comparison.

	JAS	OLYMPUS
Device Name	ISE Reagent Pack for XL-200 Clinical Chemistry Analyzer	ISE Reagents for Olympus AU 400 & 600 series chemistry analyzers
Manufacturer	JAS Diagnostics	Beckman Coulter (Olympus)
FDA 510k #	K130915 (Pending)	K981743
	JAS	**OLYMPUS**
Classification	Moderate (Pending)	Moderate
Intended Use	quantitative measurement of sodium, potassium and chloride concentrations in serum on the XL-200 clinical chemistry analyzer. *For clinical laboratory use*	quantitative measurement of sodium, potassium and chloride in serum and urine on Beckman Coulter clinical chemistry analyzers. *For clinical laboratory use*
Methodology	Ion Selective Electrodes (ISEs)	Ion Selective Electrodes (ISEs)
Reagent Description	***ISE Reagernt Pack:** **Calibrant A, 520mL:** (Na 140.0, K 4.00, Cl 125.0 mmol/L) **Calibrant B, 190mL:** (Na 70.0, K 8.00, Cl 41.0 mmol/L) ***REF 5421 Cleaning Solution**	ISE Buffer, PN: AUH1011 ISE Reference, PN: AUH1013 ISE Mid Standard, (PN:AUH1012) Internal Reference Solution, (PN: AUH1017) ISE Low Standard, PN: 1014 ISE High Standard, PN: 1015 Na Selectivity Check, PN: AUH1018

ELECTRODES

XL-200 Clinical Chemistry Analyzer	Beckman Coulter Olympus 400 Electrodes
*REF 5201: Na Electrode	MU9194: Na Electrode
*REF 5202: K Electrode	MU9195: K Electrode
*REF 5207: Cl Electrode	MU9196: Cl Electrode
*REF 5204: Reference Electrode	

JAS Expected values/Reference ranges:		Olympus Expected values/ Reference ranges:
Sodium:	136 to 145mmol/L	136 to 145mEq/L
Potassium:	3.5 to 5.1mmol/L	3.5 to 5.1mEq/L
Chloride:	98 to 107 mmol/L	98 to 107 mEq/L

15.) Performance Characteristics – ISE

Linearity (serum)

Protocol: Serial Dilutions of a Stock Standard were prepared for Sodium, Potassium and Chloride and run on the XL-200 Clinical Chemistry Analyzer. Results were then plotted as a regression graph against theoretical recovery.

Results: Slopes and Intercepts resulted for Sodium, Potassium and Chloride, linear within allowable nonlinearity of 3mg/dL or 5%; validating the products' below claimed linearity ranges.

Sodium	100 to 200 mEq/L
Potassium	1.0 to 10.0 mEq/L
Chloride	50 to 150 mEq/L

Calibrator Traceability:

Protocol: Verichem Laboratories Matrix Plus Chemistry Reference Kit (9500) five level reference material was run on the XL-200 Clinical Chemistry Analyzer, for XL-200 Sodium, Potassium, and Chloride. This material is "Verified and lot certified using available standard reference materials for the National Institute of Standards and Technology (NIST); for Calibration Verification"

Results:
Program's Evaluation of Results states Sodium, Potassium, and Chloride accuracy tests passed and results linear; with the following statistics:

Test	Slope	Intercept	Error
Sodium	1.007	4.4mmol/L	0.1%
Potassium	0.902	0.1mmol/L	1.3%
Chloride	1.012	2.0mmol/L	1.3%

Precision:

Protocol: Precision was performed using "EP Evaluator's NCCLS EP5-T2 Precision document (NCCLS.EP5)" program. Three sodium, potassium and chloride sample levels were run 20 times in duplicate, using 20 runs over a 20 day period on the XL-200 Clinical Chemistry Analyzer, for within run and for total imprecision calculation/determination.

Results: Results were entered into Rhoads EP Evaluator Software for determining precision S.D. and CV levels. All results below meet requirement of CV (%) < 5% for both within and total precision.

Sodium

Within Run:	Level 1	Level 2	Level 3
Mean (mmol/L)	118.2	131.5	166.6
S.D. (mmol/dL)	0.340	0.40	0.82
C.V. (%)	0.3	0.3	0.5
Total:			
S.D. (mmol/L)	0.808	1.08	1.36
C.V. (%)	0.7	0.8	0.8

Potassium

Within Run:	Level 1	Level 2	Level 3
Mean (mmol/L)	1.84	3.43	6.13
S.D. (mmol/L)	0.035	0.011	0.038
C.V. (%)	1.9	0.3	0.6
Total:			
S.D. (mmol/L)	0.038	0.026	0.066
C.V. (%)	2.1	0.8	1.1

Chloride

Within Run:	Level 1	Level 2	Level 3
Mean (mmol/L)	88.3	108.5	120.0
S.D. (mmol/L)	0.45	0.68	0.301
C.V. (%)	0.5	0.6	0.3
Total:			
S.D. (mmol/L)	0.73	0.80	0.559

C.V. (%)	0.8	0.7	0.5

Interferences

Protocol: Serial dilutions were prepared using a high interferent sample material, with the same sample material (sodium, potassium and chloride level respectively) without the interferent spiked. Acceptable interference level is the is the highest interferent sample level were the glucose values remains within 10% of the sample value unspiked with the intereferent.

Results: The following highest interferent levels for the sample, with < 10% interferent were obtained.

Reagent	Hemolysis	Lipemia	Bilirubin
Sodium	Hemolyzed samples should not be used	1084 mg/dL	22.5 mg/dL
Potassium	Hemolyzed samples should not be used	1084 mg/dL	22.5 mg/dL
Chloride	Hemolyzed samples should not be used	1084 mg/dL	22.5 mg/dL

Method Comparison Studies: (versus Olympus reagent on Olympus 400 analyzer)

Protocol: Multiple serum samples, at various analyte levels, were run on multiple days through the test's analytical range on the XL-200 clinical chemistry analyzer using JAS reagent packs (y method) and also on the Beckman Coulter Olympus 400, using Olympus ISE solution as a reference instrument (y method). Results were compared using a correlation plot.

Results: The following acceptable statistics resulted, i.e. R > 0.95, Slope between 0.90 and 1.10, and intercept close to 0 mg/dL level

Sodium

Number of sample pairs:	101
Range tested: x method	103 to 193 mmol/L
Range tested: y method	101 to 190 mmol/L
Correlation Coefficient	0.9917
Slope:	0.984
Intercept:	2.256 mmol/L

Potassium

Number of sample pairs:	90
Range tested: x method	1.2 to 9.90 mmol/L
Range tested: y method	1.1 to 10.0 mmol/L
Correlation Coefficient	0.9954
Slope:	0.999
Intercept:	0.05 mmol/L

Chloride

Number of sample pairs:	88
Range tested: x method	51 to 140 mmol/L
Range tested: y method	51 to 145 mmol/L
Correlation Coefficient	0.9856
Slope:	1.070
Intercept:	- 4.3 mmol/L

The submitted information in this pre-market notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

JAS DIAGNOSTICS, INC.
DAVID JOHNSTON
VP, RESEARCH AND DEVELOPMENT
14100 N.W. 57TH COURT
MIAMI LAKES FL 33014

Re: K130915
Trade/Device Name: JAS Glucose Reagent
ISE Reagent Pack
XL-200 Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JGS, CEM, CGZ, JJE
Dated: April 30, 2014
Received: May 2, 2014

Dear Mr. David Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k130915

Device Name
XL-200 Clinical Chemistry Analyzer, JAS Glucose Reagent, ISE Reagent Pack

Indications for Use *(Describe)*

The XL-200 Clinical Chemistry Analyzer is an automated random access, computer controlled, bench top, clinical analyzer for clinical chemistry tests. The instrument provides in vitro quantitative measurements for glucose, sodium, potassium and chloride in serum. This device is intended for clinical laboratory use.

The JAS Glucose Reagent is intended for the in vitro quantitative measurement of glucose in serum on the XL-200 clinical chemistry analyzer. This device is intended for clinical laboratory use. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and of pancreatic islet cell Carcinoma.

The ISE Reagent Pack is intended for the in vitro quantitative measurement of sodium, potassium, and chloride concentrations in serum on the XL-200 clinical chemistry analyzer. This device is intended for clinical laboratory use.

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus and other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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